REMARKS

I. INTRODUCTION

Claims 1, 3-5 and 7-10 are currently pending in the present application. The Examiner has rejected claims 1-10 under 35 U.S.C. § 103(a). By the present amendment, the specification and claims 1, 3, 5, 7 and 9 have been amended, and claims 2 and 6 have been cancelled without prejudice. Claims 1 and 5 have been amended to include the limitations of now-cancelled claims 2 and 6, respectively. No new matter has been added by the current amendment. Applicant respectfully submits that the pending claims are now in condition for allowance.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with Markings to Show Changes Made**."

II. AMENDMENT TO SPECIFICATION

The Examiner has noted that the incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication, is improper. As suggested by the Examiner, Applicant has herein amended the specification to replace the reference to the German Patent No. 42 26 974 with its U. S. equivalent, U. S. Patent No. 5,607,830.

III. REJECTIONS UNDER 35 U.S.C. §103 (a)

The Examiner has rejected claims 1-10 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,643,193 ("Papillon *et al.*") in view of U.S. Patent No. 5,744,047 ("Gsell *et al.*") and U.S. Patent No. 5,607,830 ("Biesel *et al.*"). Applicant

respectfully submits that this rejection should be withdrawn for at least the following reasons.

In order for a claim to be rejected for obviousness under 35 U.S.C. § 103(a), not only must the prior art teach or suggest each element of the claim, but the prior art must also suggest combining the elements in the manner contemplated by the claim. *See Northern Telecom, Inc. v. Datapoint Corp.*, 908 F. 2d 931, 934 (Fed. Cir. 1990), *cert. denied* 111 S.Ct. 296 (1990); *In re Bond*, 910 F. 2d 831, 834 (Fed. Cir. 1990). The Examiner bears the initial burden of establishing a *prima facie* case of obviousness. *See* M.P.E.P. §2142. To establish a *prima facie* case of obviousness, the Examiner must show, *inter alia*, that there is some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the references and that, when so modified or combined, the prior art teaches or suggests all of the claim limitations. *See* M.P.E.P. §2143. Applicant respectfully submits that the Examiner has not established a *prima facie* case of obviousness.

Papillon *et al.* is directed to an apparatus for the collection, washing and reinfusion of shed blood. According to Papillon *et al.*, the number of components and steps needed to collect, wash and reinfuse blood is reduced in the apparatus of Papillon *et al.* "by modifying the centrifuge bowl and locating it between the surgical site and the vacuum source." Papillon *et al.*, col. 2, lines 63-64. The apparatus of Papillon *et al.* includes a tube 10 for collecting blood from a surgical site, connected via a coupling 11 to an aspiration line 12 which "connects to the inlet port 22 of a centrifuge bowl 25, which is itself part of a centrifuge apparatus 24 that comprises the bowl 25 and means for rotating the bowl which are not shown." Papillon *et al.*, col. 4, lines 7-10. According to Papillon *et al.*, a vacuum source 34 applies negative pressure thereby drawing blood from the surgical site into tube 10,

coupling 11, and aspiration line 12, where the blood then "enters input port 22 and passes through the filter 42 into the separation chamber 48 of centrifuge bowl 25, which is rotating at about 2000 to 3000 rpm." Papillon *et al.*, col. 4, lines 61-63. Thus, the filter 42 is contained within the centrifuge bowl 25 of Papillon *et al.*

As described in the present specification, Gsell *et al.* describes a leukocyte filter which is also used for autologous blood transfusions. Gsell *et al.* describes a filter assembly including "a housing, having an inlet and an outlet, and a filter element disposed in the housing for decreasing the leucocyte content and removing other deleterious matter from a leucocyte-containing liquid," such as blood. Gsell *et al.*, col. 4, line 57 to col. 5. line 3.

Biesel *et al.* is directed to a method for the continuous conditioning of a cell suspension. According to the method and apparatus disclosed in Biesel *et al.*, "the cell suspension is centrifuged and the separated components of the cell suspension are separately removed." Biesel *et al.*, col. 1, lines 11-13. As described above regarding the amendment to the specification, the current specification has been amended to incorporate Biesel *et al.* (U.S. Patent No. 5,607,830) by reference, which is the U.S. equivalent of the previously cited German Patent No. 42 26 974.

In contrast to the teachings of Papillon *et al.* in view of Gsell *et al.* and Biesel *et al.*, the autotransfusion set of the present invention, as currently recited in independent claims 1 and 5 in amended form, includes a filter means "arranged in the blood supply line of the tubing system." Likewise, the method of the present invention, as currently recited in independent claim 9 in amended form, includes "passing the blood through a blood supply line including a filter." That is, according to the present invention, the filter for elimination

of leukocytes and/or tumor cells is arranged in the blood supply line leading to the separation unit of the autotransfusion set. As described in the present specification, although "leukocytes and/or tumor cells can be eliminated in principle before or after processing the blood[,] . . . eliminating the leukocytes before processing reduces the quantity of products of leukocyte activation or traumatization of the blood product for transfusion," and is therefore preferred. Specification, page 3, lines 9-13.

Thus, Papillon *et al.* in view of Gsell *et al.* and Biesel *et al.* do not teach nor suggest an autotransfusion set including a filter means "arranged in the blood supply line of the tubing system," or a method of autologous blood transfusion including "passing the blood through a blood supply line including a filter." Therefore, Papillon *et al.* in view of Gsell *et al.* and Biesel *et al.* do not disclose nor suggest each and every element of the presently claimed invention, and Applicant respectfully submits that claims 1, 3-5 and 7-10 are thus not rendered obvious by these patents.

Although the Examiner has alleged that "[i]t would have been obvious to one of ordinary skill in the art to provide the Papillon *et al.* blood processing system with a high capacity filter as taught by Gsell *et al.* in order to increase the amount of blood processed[, and to] . . . provide the Papillon *et al.* system with a continuously operating centrifuge as taught by Biesel *et al.* to eliminate the need to remove or drain the centrifuge bowl and to provide a system that is also capable of operating with small amounts of blood as would be seen with infants" (Office Action mailed 3/28/03, page 3, paragraph 7), Applicant respectfully disagrees. Applicant respectfully submits that the Examiner's conclusion of obviousness is improperly based on hindsight reasoning. *See In re McLaughlin*, 443 F.2d 1392, 170 U.S.P.Q. 209 (C.C.P.A. 1971). That is, the Examiner has not pointed to any prior

art teaching nor suggestion regarding the desirability of the specifically claimed combination of components and method steps which comprise the autotransfusion set and method of autologous blood transfusion, respectively, of the present invention. Although the Applicant's own disclosure teaches the desirability of such specifically claimed combinations, the Examiner may not properly rely upon "knowledge gleaned only from Applicant's disclosure" in constructing the obviousness rejection. *In re McLaughlin*, 443 F.2d 1392, 1395, 170 U.S.P.Q. 209, 212 (C.C.P.A. 1971).

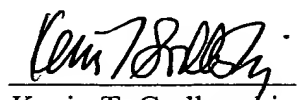
For at least the preceding reasons, Applicant respectfully submits that the rejection of pending claims 1, 3-5 and 7-10 under 35 U.S.C. § 103(a) has been overcome and should therefore be withdrawn.

IV. CONCLUSION

Applicant respectfully submits that the pending claims are in condition for allowance and requests that such action be taken. If for any reason the Examiner believes that prosecution of this application would be advanced by contact with the Applicant's attorney, the Examiner is invited to contact the undersigned at the telephone number given below.

Respectfully submitted,

Dated: June 23, 2003

By: 

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

The paragraph beginning on page 4, line 26 has been amended as follows:

Separation unit 2 is a centrifuge chamber with an annular channel 4 having an inlet 5 for the blood to be processed and an outlet 6 for the concentrated cell fraction, e.g., an erythrocyte concentrate. Such a centrifuge chamber is described in detail in ~~German Patent No. 42 26 974~~ U.S. Patent No. 5,607,830, for example, which is incorporated herein by reference.

IN THE CLAIMS:

Claims 2 and 6 have been cancelled without prejudice.

Claims 1, 3, 5, 7 and 9 have been amended as follows:

1. (amended) A device for autologous blood transfusion comprising:

an autotransfusion set including a separation unit for concentrating a cell fraction, a tubing system for providing a connection to a blood supply, and a filter means for eliminating at least one of leukocytes and tumor cells, the tubing system including a blood supply line leading to the separation unit for supplying blood to be processed, and a return line leading away from the separation unit for supplying the concentrated cell fraction, wherein the filter means is arranged in the blood supply line of the tubing system; and

a centrifuge unit, the separation unit of the autotransfusion set being rotatably mounted to the centrifuge unit.

3. (amended) The device of claim ~~2~~ 1, wherein the autotransfusion set further includes a blood collecting tank having an inlet and an outlet, the blood supply line includes a first section connected to the inlet of the collecting tank and a second section connected to the outlet of the collecting tank, and the filter means is arranged in the collecting tank.

5. (amended) An autotransfusion set for a device for autologous blood transfusion comprising:

a separation unit for concentrating a cell fraction;

a tubing system including a blood supply line leading to the separation unit for supplying blood to be processed, and a blood return line leading away from the separation unit for supplying the concentrated cell fraction, and

filter means for eliminating at least one of leukocytes and tumor cells, wherein the filter means is arranged in the blood supply line of the tubing system.

7. (amended) The autotransfusion set of claim ~~6~~ 5, wherein the tubing system further includes a blood collecting tank having an inlet and an outlet, the blood supply line includes a first section connected to the inlet of the collecting tank and a second section connected to the outlet of the collecting tank, and the filter means is arranged in the collecting tank.

9. (amended) A method of autologous blood transfusion comprising the steps of:

collecting a quantity of blood from a patient;

passing the blood through a blood supply line including a filter;

passing the blood through ~~a~~ the filter to eliminate at least one of leukocytes and tumor cells;

centrifuging the filtered blood in order to concentrate a cell fraction, and returning the concentrated cell fraction to the patient.